TRANSLATION PATENT COOPERATION TREATY POT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference										
FP0505	FOR FURTHER ACTION	See Form PCT/IPEA/416								
International application No.	International filing date (day/mon	th/year) Priority date (day/month/year)								
PCT/JP2005/001840	08.02.2005	09.02.2004								
International Patent Classification (IPC) or nation	International Patent Classification (IPC) or national classification and IPC									
C12Q1/68(2006.01), C12N15/10(2006.01), G01N33/50(2006.01)										
Applicant										
FUSO PHARMACEUTICAL INDUSTRIES, LTD.										
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This report is the international prelin under Article 35 and transmitted to the content of		shed by this International Preliminary Examining Authority								
2. This REPORT consists of a total of _	5 sho	eets, including this cover sheet.								
3. This report is also accompanied by Al	NNEXES, comprising:									
a. (sent to the applicant and	to the International Bureau) a total	of 2 sheets, as follows:								
1 1 1 1 1		h have been amended and are the basis for this report and/or								
Instructions).	curreations authorized by this Auth	ority (see Rule 70.16 and Section 607 of the Administrative								
the disclosure in the	sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental									
Box.										
b. (sent to the International l	Bureau only) a total of (indicate typ	e and number of electronic carrier(s))								
		, containing a sequence listing and/or tables								
	related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).									
This report contains indications relations	ng to the following items:									
Box No. I Basis of the	report									
Box No. II Priority										
Box No. III Non-establis	shment of opinion with regard to no	ovelty, inventive step and industrial applicability								
Box No. IV Lack of unit	y of invention									
	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement									
Box No. VI Certain doct	Certain documents cited									
Box No. VII Certain defe	Box No. VII Certain defects in the international application									
Box No. VIII Certain obse	III Certain observations on the international application									
Date of submission of the demand	Date of con	apletion of this report								
Date of submission of the demand	Date of con	aparton of this report								
Name and mailing address of the IPEA/JP	Authorized	officer								
Facsimile No.	Telephone 3	No.								

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2005/001840

Вох	No. I	Basis of the report							
1.		n regard to the language, this report is based on the intercated under this item.	national application in the language in	which it was filed, unless otherwise					
			report is based on translations from the original language into the following , this the language of a translation furnished for the purposes of:						
		international search (Rule 12.3 and 23.1(b))							
		publication of the international application (Rule	2 12.4)						
		international preliminary examination (Rule 55	2 and/or 55.3)						
2.	recei	n regard to the elements of the international application iving Office in response to an invitation under Article report):		v					
		the international application as originally filed/furnish	ed						
	\boxtimes	the description:							
		pages _ 1-29		as originally filed/furnished					
		pages*							
		pages*	received by this Authority on						
	\boxtimes	the claims:							
				as originally filed/furnished					
				er with any statement) under Article 19					
			received by this Authority on						
		nos.*							
	\square	the drawings:							
				as originally filed/furnished					
			received by this Authority on						
	\square		received by this Authority on						
		a sequence listing and/or any related table(s) – see Sup	oplemental Box Relating to Sequence I	isting.					
3.	\boxtimes	The amendments have resulted in the cancellation of:							
		the description, pages							
		the claims, nos. 2, 4	the claims, nos. 2, 4						
		the drawings, sheets/figs	the drawings, sheets/figs						
		the sequence listing (specify):							
		any table(s) related to sequence listing (specify):							
4.		This report has been established as if (some of) the a they have been considered to go beyond the disclosure							
		the description, pages							
		the claims, nos.							
		the drawings, sheets/figs							
		the sequence listing (specify):							
		any table(s) related to sequence listing (specify):							
*	If ite	rm 4 applies, some or all of those sheets may be marked	"superseded."						

PCT/JP2005/001840

Вох	k No. V Reasoned statemen citations and explai				h regard to novelty, inventive step or industrial applicability; statement	
1.	Statement					
	Novelty (N)	Claims	1,	3,	5-20	YES
		Claims				NO
	Inventive step (IS)	Claims				YES
		Claims	1,	3,	5-20	NO
	Industrial applicability (IA)	Claims	1,	3,	5-20	YES
		Claims				_ NO

2. Citations and explanations (Rule 70.7)

Document 1: JP 8-173192 A (Hamamatsu Photonics K.K.), 9 July 1996

Document 2: JP 2000-504213 A (Flinders Technologies Pty Ltd.), 11 April 2000

Document 3: WO 01/081541 A2 (Research Development Foundation), 1 November 2001

The inventions set forth in claims 1, 3 and 5 to 18 do not involve an inventive step in the light of documents 1 to 3 cited in the international search report.

Documents 1 to 3 set forth in situ PCR wherein a sample containing cells is immobilized on a support, the nucleic acid contained in said sample is exposed by treatment which uses a surfactant and/or enzymes, the nucleic acid in said sample on said support is amplified, and a judgment is made as to whether the amplified nucleic acid is a target nucleic acid (see, in particular, document 1, claims 1 to 4; document 2, page 13, line 5 to page 26, line 2; document 3, examples 2 and 3).

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claims 1, 3, 5, 6, 9 to 11 and 18 to 20

At the time of filing of this application, it was a known technique to use a support having separated compartments such as porous plates or strip wells in order to process a large number of samples simultaneously.

In addition, in in situ PCR, the target nucleic acid is detected directly on the sample after PCR, but a judgment as to whether the amplified nucleic acid present in the PCR reaction solution is the target nucleic acid is made in normal PCR, and there is nothing preventing a person skilled in the art from employing a method carried out in normal PCR for the detection of nucleic acid amplified in in situ PCR.

It would therefore be easy for a person skilled in the art to employ a support having separate compartments to process a large number of samples simultaneously and use said support to immobilize cells, and to make the judgment whether the amplified nucleic acid present in the PCR reaction solution is a target nucleic acid, in the in situ PCR set forth in documents 1 to 3.

Claim 7

At the time of filing of this application, it was a known technique in the field of devices for detecting targets on supports to adhere a reagent for detection beforehand to said support, therefore it would be easy for a person skilled in the art to conceive of immobilizing beforehand the gene fragments used for detection on the support of the inventions set forth in documents 1 to 3.

International application No.
PCT/JP2005/001840

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Claim 8

At the time of filing of this application, it was a known technique to use a DNA micro-array to detect the presence of a target nucleic acid.

It would therefore be easy for a person skilled in the art to conceive of the invention set forth in claim 8 of this application based on the inventions set forth in documents 1 to 3 and said known technique.

Claims 14 to 17

It would be easy for a person skilled in the art to conceive of employing the methods of detecting nucleic acids set forth in documents 1 to 3 to ascertain the presence of genes related to infectious diseases, cancer or hereditary diseases.